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Effectiveness of Natalizumab on Multiple Sclerosis patients: the Italian registry experience

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Background: Natalizumab (NTZ) is the first targeted humanized monoclonal antibody to be approved for the treatment of relapsing-remitting multiple sclerosis (RRMS). According to the current literature, NTZ appears to be one of the most effective drug among the MS disease-modifying therapies. In our study, we aimed to evaluate the efficacy outcomes in a large Italian population of RRMS patients treated with NTZ.

Materials: this is a large retrospective, multicentre, Italian study. Data from 51,845 patients from 69 Italian multiple sclerosis centres were extracted from the iMedWeb registry in May 2018.

Methods: we included MS patients with at least six NTZ infusions and the availability of a minimal data set consisting of: sex, date of birth, date of multiple sclerosis onset, dates of clinical relapses occurring in the year preceding NTZ initiation (T0) and at the last evaluation during NTZ treatment (T1), and Expanded Disability Status Scale (EDSS) score recorded at the time of the first and last NTZ infusions. Any invalid or inconsistent entries were identified and excluded in a series of automated filtering steps.

Result: the final population entering the analysis included 5,486 patients; 3,799 (69.2%) were females, with mean age 41.4±10.4 years (median 42.3), disease duration 12.4±7.5 years and an observation period of 7.0±5.9 person-years. At T1, the annualized relapse rate (ARR) was significantly reduced (2.02±0.3 versus 0.65±0.5, p<0.01), with 3,697 (67.4%) patients reached 'No evidence of disease activity' (NEDA-2). No differences in terms of EDSS from T0 and T1 were observed. Stratifying according to the age and the EDSS at the time of the first NTZ infusion, we found that patients older than 40 years and patients with an higher EDSS showed higher ARR and EDSS at last follow up visit. Moreover, a lower percentage of patients older than 40 years reached the NEDA-2 compared to the youngest ones (2,374 [75.7%] versus 1,323 [56.3%], p<0.05); similarly, a lower percentage of patients with EDSS higher than 4.0 reached the NEDA-2 status compared to patients with EDSS lower than 4.0 (1,219 [60.4%] versus 2,478 [71.5%], p<0.05).

Discussion: our data provides further support for the efficacy of NTZ in the clinical practice setting. The effect of NTZ treatment on the relapse rate and on the progression of disability seems to be more pronounced in younger and with less

disability patients at the time of NTZ initiation.

Disclosure: All Authors declare no conflict of interest